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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/681,753 | 05/31/2001 | James Norman Cawse | RD-28169 | 6423 |

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EXAMINER

CLOW, LORI A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/681,753

Applicant(s)

CAWSE, JAMES NORMAN

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-20, 26 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14-20, 26, and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 5 March 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-9, 14-20, 26, and 35-40 are currently pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 14-20, 26, and 35-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility. *This is a new grounds of rejection.*

Claims 1-9, 14-20, 26, and 35-39 are directed to a method to conduct an experiment based on selecting, estimating, assign, effecting, and adjusting. However it is not clear what result is produced by the said method. The "usefulness" of a method to conduct an experiment without a result is not apparent, as there is no step of actually conducting an experiment leading to a particular result. Original claim 13 included a step of "evaluating the products to **select a lead from the library**" and the specification teaches that the invention can be used to identify an "active and selective catalyst for the production of aromatic carbonates. The procedure includes combination of a experimental team weighting procedure and a CHTS method **to identify a best**

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catalyst from a complex chemical space, where the chemical space is defined as an assemblage of possible experimental conditions defined by a set of variable parameters such as formulation ingredient identity or amount or process parameter such as reaction time, temperature, or pressure” (page 8).

However, the usefulness of claims directed merely to a method to conduct an experiment comprising selecting factors, estimating interactions, assigning probabilities, effecting CHTS, and adjusting probabilities remains unclear. It is noted that in order for this method to be useful for these purposes, other information is required, such as identification of an actual use. Utilities that carry out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities (See MPEP 2107.01). Further, as set forth in *Brenner v. Mason* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), the “usefulness” of an invention must be immediately apparent to those familiar with the technological field of the invention. As further research, mathematical calculations, and method steps would be required to “use” the instant method and system the apparent result of the method and system is not “immediately useful” and lacks utility.

Claims 1-9, 14-20, 26, and 35-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 20, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains rejected for the reasons set forth on the previous Office Action.

Claim 20 recites “reiterating (A)”. There is insufficient antecedent basis for (A) in the claim, as claim 16, from which claim 20 depends, does not include a step (A).

It is unclear in claim 40 how the step of reiterating the CHTS method until a catalyst composition lead is selected is performed. What are the parameters that indicate when the reiteration stops and a lead can be selected? Is there an additional step?

Response to Applicant’s Arguments

Claim Rejections - 35 USC § 101-Non-Statutory

Applicant argues that “arguments of the PTO relating to this objection refer to mathematical algorithm”. Further Applicant states that “a method to conduct an experiment is a new and useful process”. This argument is not persuasive for the reasons set forth in the previous Office Action. Specifically, MPEP 2106 states that “for such subject matter to be statutory, the claimed process **must be limited to a practical application of the abstract idea** or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d

at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing *O’Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible, and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible, and useful”. In the instant claims, there is no specificity identified as to what is intended by the outcome of the method. Therefore, the invention does not meet the standard of being immediately useful. Furthermore, there is no particular data identified or specific factors recited in the specification such that a concrete, tangible, useful result is readily apparent. The claims are still directed to a method in which only mathematical manipulation of data occurs. The steps of the instant claims appear to be directed to *in silico* methods and not the physical method of performing a combinatorial high throughput experiment in which physical steps are performed.

Claim Rejections - 35 USC § 112

In regard to claim 1 and dependent claims, applicant argues that “the PTO mischaracterizes the claims. The claims do not “imply that the physical steps of CHTS are somehow tied to a Latin Square model”. The claims state that “the CHTS method comprises defining a first experimental space by structuring the levels according to a Latin Square strategy”. However, claim 1 still recites “effecting a combinatorial high throughput screening (CHTS) method on an experimental space representing the levels, wherein the CHTS method comprises defining a first experimental space by structuring the levels according to a Latin

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Square strategy". It remains unclear if the CHTS experiment itself comprises a Latin Square model or if the experiment is 'effected' according to the model, as indicated in the specification.

Claim Rejections - 35 USC § 103

Claim rejections under 35 USC 103 have been withdrawn in view of Applicant's response.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

Lori A. Clow
26 May 2004

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
5/26/04